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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/849,686      08/21/97      DEGGERDAL      A      08269/003001

JANIS K FRASER  
FISH & RICHARDSON  
225 FRANKLIN STREET  
BOSTON MA 02110-2804

HM22/1012

EXAMINER

OWENS JR, H

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

19  
10/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/849,686

Applicant(s)

Deggerdal et al.

Examiner

Howard Owens

Group Art Unit

1623



☒ Responsive to communication(s) filed on Jul 13, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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*Response to Arguments*

The following is in response to the amendment filed 7/13/00:

An action on the merits of claims 1-24 is contained herein below.

**35 U.S.C. 112(2) Rejection**

The rejection of claims 13 and 19 - 21 set forth in the office action dated 5/12/99 is withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 sets forth a method "further comprising one or more additional steps to disrupt structural components in the sample or to achieve lysis of cells in the sample", however it is unclear as to what these "additional steps" are exactly as well as at what point in the method these steps are carried out.

In claim 24, the term "biochemical manipulation" does not set forth the metes and bound of the invention. The term "biochemical manipulation" lack specificity and is indefinite with regards to the number of biochemical techniques available to one of skill in the art.

**35 U.S.C. 102 Rejection**

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The rejection of claims 1, 2 and 14 under 35 U.S.C. 102(b) over Pharmacia Biotechnology Products catalog is withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

5 A person shall be entitled to a patent unless --

10 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-4, 9-11, 13, 16-18, 20, 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Cros et al., U.S. Patent No. 5,510,084.

15 The instant claims are drawn to a method of isolating nucleic acid from a sample by contacting the sample with a detergent and a solid support in the absence of any chaotropic agent and separating the nucleic acid from the sample, wherein the solid support can be a porous, particulate, organic polymer.

20 Cros anticipates these claims as it teaches the use of an organic polymeric support in the separation and isolation of nucleic acids of either DNA or RNA .Cros et al. teach the use of natural or synthetic materials which may or may not be chemically modified as solid supports such as nylon or polyacrylate. Cros et al. teach polymers such as polydivinylbenzene, polystyrene, polypropylenes, polyethylene and copolymers thereof as preferred supports for the immobilization of nucleic acids in  
25 diagnostic tests, affinity chromatography and in separation processes (col.4, line 17 - col.5, line 4). Cros et al. also teaches the use of detergents such as alkaline sodium phosphate in the isolation process (see Example 12).

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**35 U.S.C. 103 Rejections**

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Cros et al., U.S. Patent No. 5,510,084 and the 1994 Pharmacia Biotechnology Products Catalog already of record.

Applicant's arguments filed 7/13/00 in response to the rejection of claims 1-12 and 14-18 under 35 U.S.C. 103(a) as being unpatentable over the 1994 Pharmacia Biotechnology Products Catalog., have been fully considered but they are not persuasive. The maintenance of the rejection of claims 1-12 and 14-18 under 35 U.S.C. 103(a) and the inclusion of claims 13 and 19-24 under 35 U.S.C. 103 is set forth below.

Applicant's claim that the targeting of the Pharmacia product is limited to mRNA tails is countered by the inclusion of "fractionization of oligonucleotides" apart from mRNA isolation set forth in the Pharmacia catalog clearly indicating that nucleic acids are within the scope of the invention.

With regards to the reference suggesting all of the limitations specifically the presence of a detergent and in the absence of a chaotropic agent, as cited previously "The Pharmacia Catalog discloses Oligo(dT) Cellulose which is an organic support which can bind nucleic acids in the presence of a detergent, buffers, salt, and chelating agents, then elute said nucleic acid upon heating". There is no evidence that one of skill in the art could not use the claimed Pharmacia invention in the absence of chaotropic agents. One of the facets of determining obviousness is not only determining the scope and contents of the prior art, but resolving the level of ordinary skill in the pertinent art.

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As noted by applicant inherency can only be established if it is recognized by persons of skill in the art that the missing descriptive matter is present in the reference.

As recited from the previous office action, the Pharmacia Catalog discloses oligo(dT) Cellulose (Product Code No. 27-5543-01) for the isolating of mRNA from a cell lysate which can certainly contain any conventional detergent. Oligo(dT) Cellulose is certainly an organic support which can bind mRNA in the presence of detergents. Furthermore, the material can be washed and the nucleic acid eluted with heat which simply denatures the double-stranded nucleic acid. One of skill in the art would clearly recognize that clearly recognize the common use of detergents within the art of purification of nucleic acids; moreover, that the Pharmacia product could be used in the absence of a chaotropic agent, barring evidence to the contrary, which has not been presented by applicant; moreover, detergents listed in the specification (p.8) such as Tris, Bicine, Tricine and phosphate buffers have been routinely used in this art for the preparation, isolation or separation of nucleic acids (see Cros et al cited below). Given this, one of skill in the art would clearly recognize the common use of detergents within the art of purification of nucleic acids.

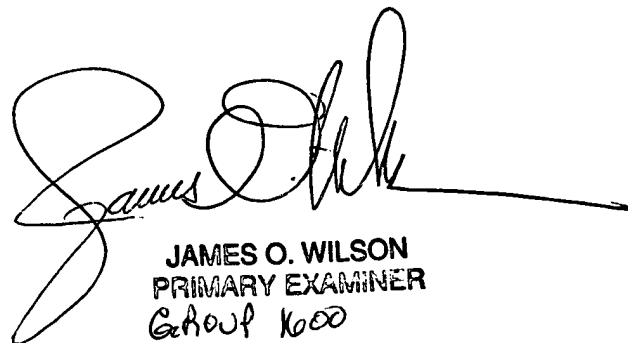
In support of the Pharmacia Product catalog, the Cros et al. reference is provided to show the obviousness of the use of solid supports and non-chaotropic buffers in the isolation or separation of nucleic acids. Cros et al. teaches the use of an organic polymeric support in the separation and isolation of nucleic acids of either DNA or RNA. Cros et al. teach the use of natural or synthetic materials which may or may not be chemically modified as solid supports such as nylon or polyacrylate. Cros et al. teach polymers such as polydivinylbenzene, polystyrene, polypropylenes, polyethylene and copolymers thereof as preferred supports for the immobilization of nucleic acids in diagnostic tests, affinity chromatography and in separation processes (col.4, line 17 - col.5, line 4). Cros et al. also teaches the use of detergents such as alkaline sodium phosphate in the isolation process (see Example 12).

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Any inquiry concerning this communication or earlier  
communications from the examiner should be directed to Howard Owens  
5 whose telephone number is (703) 306-4538 . The examiner can normally be  
reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful,  
the Primary Examiner signing this action, James O. Wilson can be reached  
10 on (703) 308-4624 . The fax phone number for this Group is (703) 308-  
4556.

Any inquiry of a general nature or relating to the status of this  
application or proceeding should be directed to the Group receptionist  
whose telephone number is (703) 308-1235.

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JAMES O. WILSON  
PRIMARY EXAMINER  
Group 1623

Howard Owens

Group 1623